

REMARKS

In the Supplemental Examiner’s Answer, the Examiner set forth a new ground of rejection. Specifically, the Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being obvious over U.S. Pub. No. 2003/0036689 to Diab et al. (“Diab”) in view of U.S. Pat. No. 5,662,106 to Swedlow et al. (“Swedlow”) and in further view of non-patent literature “Masimo Signal Extraction Pulse Oximetry” (“Masimo”). The Examiner also indicated that claims 5 and 17 include allowable subject matter. While, Appellant thanks the Examiner for pointing out the allowable subject matter, Appellant maintains that all pending claims are in condition for allowance. Accordingly, Appellant submits the following remarks and requests allowance of all pending claims.

Request to Reopen Prosecution

As admitted by the Examiner, the Supplemental Examiner’s Answer includes new grounds of rejection. *See* Supplemental Examiner’s Answer, p. 4. However, 37 C.F.R. § 41.43(a)(2) clearly states that “[a] supplemental examiner’s answer responding to a reply brief may not include a new ground of rejection.” Accordingly, Appellant requests that the appeal be withdrawn and that prosecution be reopened in accordance with 37 C.F.R. § 41.39(b) and M.P.E.P. § 1207.03.

Rejection Under 35 U.S.C. § 103

In the Supplemental Examiner’s Answer (“the Supplemental Answer”), the Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as obvious over Diab in view of Swedlow and further in view of Masimo. Specifically, the Examiner stated the following:

With respect to claims 1-4, 6-16, 18-22, the Diab et al. patent teaches a system for detecting the presence of mixed venous and arterial blood pulsation in tissue, (abstract, paragraph 0019), obtaining a measure of a phase difference between said first and second electromagnetic radiation signals (paragraphs 0389-0391, fig. 25B, elements 694, 692, 690), comparing said measure with a threshold value to form a comparison (paragraph 0387, fig. 25B, elements 660, 662, 696); and detecting the presence or absence of venous pulsation using said comparison (paragraphs 0019, 0368). (NOTE: it is well known in the art that the primary cause of noise in

transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger ...).

Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present. However, the Swedlow et al. patent teaches an indication of the presence of venous pulsation to a caregiver if venous pulsation is present (see abstract, fig. 1, element 30, and figure 4, col. 5, line 64 – col. 6, line 34).

It would have been obvious for a person of ordinary skill in the art, to modify the system disclosed by Diab et al., with the above discussed enhancements because such modification would provide a more accurate blood oxygen and pulse readings.

Supplemental Answer, pp. 5-6.

Appellant respectfully traverses this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not enough to show that all the elements exist in the prior art since a claimed invention composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and it must be based on *objective evidence of record*. See *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

As has been asserted throughout prosecution, neither Diab nor Swedlow discusses detecting *venous pulsation* or indicating the presence of venous pulsation to a caregiver when detected, as recited in independent claims 1 and 13. However, the Examiner argued that Diab and Swedlow teach these limitations because “it is well known in the art that the primary cause

of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger.” Supplemental Answer, p. 5. However, Appellant asserts that venous blood movement is not the primary cause for motion artifact. Indeed, Appellant has challenged this assertion because it is clearly erroneous and has asked that the Examiner provide support for the assertion. The Examiner now asserts that this allegedly well known fact is supported by Masimo. The deficiencies of these references will be discussed in detail below.

Contrary to the Examiner’s assertions, Diab and Swedlow do not discuss *venous pulsation*. The central dispute between the Examiner and the Appellant seems to be based on the meaning of the term “venous pulsation” as recited in independent claims 1 and 13 and as described in the present application. As discussed in the present application, venous pulsation is a phenomenon in pulse oximetry which may interfere with the calculation of various physiological parameters, such as oxygen saturation or pulse rate. Application, ¶ [0038]. Venous pulsation is generally believed to be caused by venous blood backing up and pooling due to a lack of sufficient valves in the vascular anatomy. *Id.* Venous pulsation is more common in certain areas of the body where there are fewer valves, such as the head or forehead. *Id.* In addition, a patient’s medical condition may increase the likelihood that venous pulsation will occur. *Id.* Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. *Id.*, ¶ [0039]. Venous pulsation is a *different phenomenon* from motion artifact, which may be caused by patient movement, such as shivering, finger tapping, waving, and so forth. Motion artifact can be caused by movement of the patient relative to the sensor, “such as by the detector moving away from the skin temporarily,” and essentially has nothing to do with venous pulsation. Swedlow, col. 2, lines 14-15. Indeed, a patient who is lying *perfectly still* may experience venous pulsations.

In contrast, the Diab reference discloses a system where the *venous saturation* is quantified. Specifically, the Diab reference calculates an arterial *saturation* and a venous *saturation*. See Diab, ¶ [0395]. To measure the venous saturation, Diab uses arterial saturation

values, and the venous saturation measurement appears to derive from arterial saturation measurements. *See id.* The Diab reference explains:

In order to obtain the venous *saturation*, the minimum arterial *saturation* value, of points that exhibit non-zero value, is selected rather than the maximum arterial *saturation* value. The *saturation* can be provided to the display 336.

Id. (emphasis added).

Regarding paragraph [0019] of Diab, which the Examiner cited on page 5 of the Supplemental Answer, Diab discloses that a plethysmographic wave contains primary and secondary portions. *See Diab, ¶ [0019].* The secondary portion is noise and may include *several parameters*, including patient movement, venous blood contribution to attenuation of energy as it passes through the body, and respiration. *See id.* A parameter “n” utilized in algorithms disclosed in Diab represents noise, including “information on the venous blood, *as well as motion artifacts and other noise.*” Diab, ¶ [0368] (emphasis added). Appellant stresses that the sources of noise in the secondary portion of the plethysmographic wave *are not sorted or specifically identified.* Diab does not disclose a method or means for detecting *venous pulsation* but rather discloses that a portion of the plethysmographic wave may include a hodgepodge of *various* noise signals. That is, the secondary portion of the plethysmographic wave contains a variety of noise and *may or may not* contain noise due to venous pulsation.

Claim 1 of the present application recites “obtaining a measure of a phase difference ... comparing the measure with a threshold ... detecting the presence or absence of venous pulsation using the comparison.” Claim 13 recites “means for obtaining a measure of a phase difference ... means for comparing the measure with a threshold ... means for detecting the presence or absence of venous pulsation using the comparison.” Regarding the phase difference measurement recited in claims 1 and 13, Diab discusses a type of phase difference measurement between red and IR signals; however, this measurement is not obtained to form a comparison with a threshold to *detect the presence of venous pulsation.* *See Diab, ¶¶ [0389]-[0393].* Rather, according to Diab, if the phase difference between a red and IR point is low enough, the points

are used to calculate a *saturation value*. See Diab, ¶¶ [0393]-[0394]. That is, Diab discloses calculation of arterial and venous *saturation*. See Diab, ¶ [0395]. Appellant finds no discussion in Diab regarding detecting the presence or absence of a *venous pulsation*.

Furthermore, Swedlow does not cure the deficiencies of Diab. Swedlow discloses modification of an alarm condition when *motion* is detected. See Swedlow, Abstract. *Nothing* in Swedlow discloses detection of *venous pulsation*, much less an indication of its presence. Rather, Swedlow merely discloses a pulse oximeter that detects *motion artifacts*. See Swedlow, col. 1, lines 10-13; col. 2, lines 52-53; col. 5, line 64 – col. 6, line 14. Specifically, Swedlow relates to detection of a motion artifact, “such as by the detector moving away from the skin temporarily.” Swedlow, col. 2, lines 14-15. Again, a motion artifact is not equivalent to venous pulsation as recited in the present claims. Accordingly, detection of motion artifacts *does not teach detection of venous pulsations*.

Despite the complete lack of any discussion regarding detecting the presence or absence of *venous pulsation* in either Diab or Swedlow, the Examiner continues to assert that claims 1 and 13 are obvious in view of these references. Specifically, the Examiner relied on the allegedly “well known fact” that “the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger.” Supplemental Answer, p. 5. As support for the allegedly “well known fact,” the Examiner cited Masimo.

First, it remains unclear to the Appellant exactly what the Examiner is attempting to assert by these arguments. For example, in the Supplemental Answer, the Examiner explicitly stated the following:

Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based

oximetry system. Having identified the venous blood as a significant contributor to noise during motion.

Id., p. 8. It appears that the Examiner is asserting that, because venous blood is deformed during motion, detection of motion artifact is equivalent to detecting venous pulsation. This understanding of the Examiner's position seems to be supported by the conversation during the interview between Appellant's representative and the Examiner on December 22, 2008. Indeed, Appellant's representative pointed out that the evidence submitted by the Examiner in support of the alleged "well known facts" relied upon in the rejection under 35 U.S.C. § 103(a) did not demonstrate that motion artifact and venous pulsation are equivalent or interchangeable phenomena. *See Interview Summary.* In response, the Examiner stated that the argument set forth on page 6 of the Examiner's Answer did not mention venous pulsation. *See id.* Appellant's representative reminded the Examiner that the present claims are directed to detection of venous pulsations and therefore the Examiner's statement was confusing. *See id.* Accordingly, Appellant stresses that venous pulsation is not equivalent to motion artifact and directs the Board's attention to the discussion of the meaning of venous pulsation and motion artifact set forth above, which is supported not only by the present application but also by the cited references. For example, Swedlow suggests that motion artifact results from motion of the detector relative to the tissue, such as "the detector moving away from the skin temporarily," and does not even mention venous pulsation.

Additionally, even if it was a well known fact at the time of Appellant's invention that venous blood is deformed during motion and so forth, this information does not obviate the deficiencies of Diab and Swedlow. Indeed, venous *blood* deformation caused by patient motion is not the same as venous *pulsations*. Even the reference the Examiner relied upon in support of the assertion of "well known facts" merely discloses that "*during patient motion, movement of non-arterial components* (for example, venous blood) *can be identified* as additional saturation components." Masimo, p. 476 (emphasis added). This is apparently merely directed to identification of the "movement of non-arterial components," which may include venous blood. This is *not* directed to detecting the presence or absence of *venous pulsation*. In fact, it is

apparent that Masimo is directed to identifying a “correct *arterial saturation.*” *Id.*, p. 477 (emphasis added). Further, to the extent that Masimo relates to venous pulsation in any way, it does not appear to be detecting the presence or absence of venous pulsation. Rather, at best, it appears to be lumping venous pulsation into a general category of noise. Again, motion artifact and venous pulsation are not the same phenomenon, and detection of one does not constitute detection of the other.

In summary, neither Diab nor Swedlow disclose “detecting the presence or absence of venous pulsation” as recited in independent claims 1 and 13. Additionally, neither reference discloses “indicating the presence of venous pulsation to a caregiver if venous pulsation is present.” The “well known facts” asserted by the Examiner fail to obviate the deficiencies of the cited references. Even if it was well known at the time of Appellant’s invention that “the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger,” which Appellant does not concede, this alleged fact would not render the present claims obvious over references relating to motion artifact. That is, the presence of *motion artifact* (i.e., noise due to patient movement) does not indicate the presence of *venous pulsation* (i.e., a phenomenon which can be present without any patient movement), or vice versa. In view of the above arguments, Appellant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 103 and provide an indication of allowance for all pending claims.

Conclusion

If the Examiner wishes to resolve any other issues by way of a telephone conference, the Examiner is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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